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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CFN 1121950

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 24, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jang W. Lee, President
Super Foods, Inc.
1257 4th Street, NE
Washington, DC 20002

Dear Mr. Lee:

During an inspection of your facility conducted by the Food and Drug Administration (FDA) on December 15 and 16, 1997, deviations from the Good Manufacturing Practice Regulations (GMP) (Title 21, Code of Federal Regulations (CFR), Part 110) were documented with respect to your firm's tofu and cookie manufacturing facility. By virtue of these deviations, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. At the conclusion of the inspection, Mr. Tom A. Lee, Manager, was presented with a Form FDA-483 listing these deviations.

Our inspection revealed that insanitary conditions noted during previous inspections of your facility continue. These include, among other deviations listed on the FDA-483, the following:

1. Rodent activity in the following areas:

   (a) Two pallets containing bags of soybeans stored in the first floor west side dry storage area were observed with rodent filth to include: 19 bags of soybeans with apparent rodent urine stains; 2 bags with apparent rodent gnawed holes; 29 bags covered with in excess of 189 rodent excreta pellets; and apparent rodent nesting material and rodent excreta pellets in the center of both pallets.

(b) In excess of 100 rodent excreta pellets along the west side floor juncture behind 7 pallets containing bags of soybeans in the first floor dry storage area.

2. Live cockroaches on food contact surfaces of equipment and utensils in the tofu and cookie manufacturing areas.

3. Failure to adequately wash and sanitize food manufacturing equipment and utensils before each use.

4. Failure to adequately construct food contact equipment surfaces (metal cookie dough mixer) with smooth bonded seams and, corrosion-resistant material, and properly maintain such equipment to facilitate its cleaning.

5. Failure to furnish warm running water at an employee hand washing facility located in the tofu manufacturing area.

6. An approximate one inch by one-half inch gap at the bottom of the closed metal doors leading from the outside into the dry food storage area.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge that the rodent-damaged bags of soybeans were removed from your facility. However, it is your responsibility to assure continuing adherence with the requirements of the GMP, 21 CFR 110. This includes, among other requirements, that you employ appropriate quality control operations to ensure that food is suitable for human consumption. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to assure that they are clean and suitable for processing into food, and shall be stored under conditions that will protect against contamination and minimize deterioration.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to prevent recurrence of similar violations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, Ext. 14.

Sincerely,

Carl E. Draper

Carl E. Draper
Acting Director, Baltimore District

cc: Virginia Department of Health
Division of Shellfish Sanitation
Suite 109
1500 East Main Street
Richmond, Virginia 23219